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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,774	01/30/2002	Alfred Popp	POPP ET AL - 1 US	5508

7590

09/30/2003

COLLARD & ROE, P.C.
1077 Northern Boulevard
Roslyn, NY 11576-1696

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,774

Applicant(s)

POPP ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The application should be reviewed for errors.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in that the components of the "mixture" intended are not delineated with sufficient clarity. It is apparent that two separate reaction mixtures are intended. However, the recitation at 3 lines from the bottom of "isolation ~~an~~ uncleaved enantiomer", suggests that more than one uncleaved enantiomer is envisioned. The term "the" should be replaced therefor. The phrase "an enzyme with hydrolytic activity into contact" does not specify what the enzyme is contacted with.

Claim 1 is vague, indefinite and confusing in the recitation of "derivatives" with respect to the substrates to be enzymatically transformed. It is unclear which compounds are intended to be encompassed by this terminology even when reading the claims in light of the specification.. The compounds intended are not specified with sufficient particularity.

Claim 1 is further vague, indefinite and confusing in the use of "enantiomer". The correct term appears to be "racemic" in this context.

Claim 1 is vague and indefinite in the recitation of "enantiopure", since the enantiomer to be obtained is not identified, and the degree of purity is not set forth. Generally the enantiomer is identified as "R" or "S" and enantiopurity is expressed as a percentage of "enantiomeric excess" or "ee". Claim 1 is confusing in the space at line 10. Correction is required.

Claim 1 is vague and indefinite in the recitation of "in the presence of a nucleophile", since it is doubted that the mere "presence" of a nucleophile is sufficient

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for the reaction to occur. It is recommended that the phrase --an effective amount of nucleophile to effect the biotransformation--.

Claim 2 is vague and indefinite in that the subscripts are either barely legible or illegible. Correction is required.

Claim 2 fails to find proper antecedent basis in claim 1 for "the mixture...is cleaved". An "enantiomer" is cleaved in claim 1 as written.

Claim 2 is confusing and redundant in the recitation of "Equation 5", which seems out of place.

Claim 2 encompasses an improper Markush grouping because of the use of "or" in the listing of the grouping. Conjunctive rather than alternative language should be used (e.g. selected from the group consisting of A,B, AND C). The claims as drafted do not follow this form, since the term "or" is interspersed in the listings. See MPEP 2173.05(h)(a). Also, the intended target for "substituted or unsubstituted" is not clearly delineated. Is it the first term or all? The intended substituents are not specified.

In claim 4, the intended meaning of "directly" is not set forth with sufficient particularity.

Claim 5 is confusing in the use of spaces in the numbers. It is recommended that they be replaced by ",". Also the "/" should be replaced by "or" to clarify the invention.

Claim 13 fails to find proper antecedent basis in claim 1 for "the solvent".

The claims appear to be free of the art of record.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.

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A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx
Primary Examiner
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